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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,294	09/29/2003	Thomas L. Cantor	532212001900	5531

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/674,294

Applicant(s)

CANTOR ET AL.

Examiner

Jacob Cheu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 12/18/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 9 is cancelled.
2. Claims 1-8, 10-15 are under examination. Claims 16-24 are withdrawn from further consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6-15 rejected under 35 U.S.C. 102(b) as being anticipated by Gao et al. are maintained.

Gao et al. teach a parathyroid hormone (PTH) assay control. The assay comprises a whole PTH component having amino acid 1-84 of PTH, and a PTH fragment having amino acid 7-84 of PTH which falls within the recited range, i.e. spanning position 2 through 33 of PTH of its N-terminal, and C-terminal spanning from 35 through position of 84 of PTH, where Gao et al. teach storing the PTH in lyophilized form, e.g. protein matrix base (See page 606, right column, Materials and Methods- Chemicals and Reagents). The ratio of the whole PTH to the 7-84 PTH fragment is within range about 1% to 99% (See Figure 2).

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With respect to claim 2 and 14-15, Gao et al. teach comparing the binding assay of IRMA and conventional Nichols assay by mixing the whole PTH component with the PTH fragment in a predetermined ratio (See Figure 2).

With respect to claim 3, Gao et al. using synthetic method to generate the PTH components. Supra.

With respect to claims 6-8, Gao et al. teach using lyophilized form for storage of the PTH components to prolong storage life of the PTH peptides. Surpa.

With respect to claims 9-10, Gao et al. established that there is no cross-reactivity of whole PTH with the 7-84 PTH fragment by detecting binding of these two peptides in different ration (See Figure 2).

With respect to claims 11 and 13, Tthe recitation of “instructions” is not afforded patentable weight because the recited “instructions” are not functionally related to the underlying kit, but merely teach a new use for an existing product. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-6, 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Bouillon et al. in view of Holthuis et al. are maintained.

Bouillon et al. teach a parathyroid hormone (PTH) assay control. The assay comprises a whole PTH component having amino acid 1-84 of PTH, and a PTH fragment having amino acid 23-84 of PTH which falls within the recited range, i.e. spanning position 2 through 33 of PTH of its N-terminal, and C-terminal spanning from 35 through position of 84 of PTH (See page 271, right column, Materials and Methods-Reagents). The ratio of the whole PTH and the 23-84 PTH fragment is also within the range from 1-99%. Supra. However, Bouillon et al. do not explicitly teach using protein matrix base.

Wang et al. teach using serum albumin as protein matrix base. The advantages include, to increase storage life of PTH, serving as carrier, lyophilized for reconstruction and enhance absorption (Col. 1, line 35-55).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bouillon et al. with the lyophilizer as taught by Holthuis et al. in order to increase the storage life of the PTH peptides and reconstruction for subsequent analysis.

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With respect to claim 2 and 14-15, Bouillon et al. teach comparing interfering effects of PTH fragments by mixing the whole PTH component with the PTH fragment in a predetermined ratio, e.g. excess of 1000 fold molar ratio (See page 273, right column, second paragraph).

With respect to claim 3, Buillon et al. using synthetic method to generate the PTH components. Supra.

With respect to claims 4-5, Bouillon et al. teach purifying PTH from natural sources, such as human hPTH by chromatography (See page 272, left column, second paragraph). Although Bouillon et al. teach isolate and purify hPTH (52-84), which does not fall within the recited amino acid residue range, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bouillon et al. to isolate 7-84 or 23-84 PTH since using chromatograph of isolating peptide of interest is a routine practice in the field, and a matter of time/cost consideration comparing chemical synthesis of peptide.

With respect to claims 11 and 13, Tthe recitation of “instructions” is not afforded patentable weight because the recited “instructions” are not functionally related to the underlying kit, but merely teach a new use for an existing product. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

Response to Applicant's Arguments

Gao et al. reference

6. Applicant argues that reference of Gao et al. do not teach every features of the instant invention. Particularly applicant argues that Gao et al. reference only teach lyophilized whole PTH fragment, not the PTH fragment. No known ratio of the whole PTH and its fragment is disclosed in Gao et al. reference.

Applicant's argument has been considered but is not persuasive.

The instant claim directs to a product, not a method. The main components are (a) whole PTH (1-84); (b) its fragment, with certain spanning recited range; (c) a protein matrix base. The feature of ratio of whole PTH to the PTH fragment is an inherent matter since the wide range, i.e. 1-99%, this feature would satisfy as long as both components exists. Examiner would like to point out that Gao et al. article disclose both the whole PTH and the 7-84 PTH fragment (See Materials and Method). Furthermore, the ratio range is disclosed in Figure 2 where whole PTH and 7-84 was used to compare the assay. As for the lyophilized sample (protein matrix base, such as serum), the claim language merely recites that "said composition further comprises a protein matrix base", the claim language does not require that both whole PTH and PTH fragment have the protein matrix base. Thus, all the recited features are met by the teachings in Gao et al. reference, the anticipation rejection is deemed proper.

With respect to claims 2-3, applicant argues that they further limit claim 1 and cannot be anticipated because Figure 2 (as pointed out by examiner) merely indicating whole PTH compared to 7-84 PTH fragment separately, no disclosure of Gao et al. teach a composition containing both whole PTH and PTH fragment together.

Applicant's argument has been considered but is not persuasive.

As discussed above, the instant invention directs to a product. All the materials, whole PTH and PTH fragments (including PTH (7-84), PTH(1-34), PTH(39-84), PTH(44-66), and PTH(53-84)) are part of the assay. Therefore the assay of Gao et al. include both whole PTH and PTH fragments.

Holthuis et al. reference

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7. Applicant argues that Holthuis et al. does not teach serum albumin prolongs storage life of PTH peptides. Applicant points out that Holthuis et al. in fact disclose a formulation to prolong stability by using mannitol and a citrate material.

Applicant's argument has been considered but is not persuasive.

The information from Holthuis et al. should not be limited to one or some of the Holthuis et al. embodiments. The criteria of the secondary reference used in view of 35 USC 103, are whether one ordinary skill in the art considering the overall teachings of Holthuis et al. pertinent art and within the scope of the invention (See *Graham v. John Deere Co.*). The reference of Holthuis et al. discloses advantages of using albumin are reviewed by different researchers in the field in PTH preparation. Supra. Therefore the motivation/suggestion is provided and one artisan in the art would have adapted to use albumin protein matrix to increase the overall assay efficiency.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

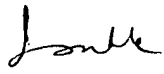
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Jacob Cheu

Examiner

Art Unit 1641

February 7 2007


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